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Marina Larson & Associates, LLC				
P.O. BOX 4928				
DILLON, CO 80435				
EXAMINER				
WOODWARD, CHERIE MICHELLE				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/537,280

## Applicant(s)

SANDERS ET AL.

## Examiner

CHERIE M. WOODWARD

## Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 121, 122, 125-139 and 141-199 is/are pending in the application.
- 4a) Of the above claim(s) 138, 141-143 and 145-197 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 121, 122, 125-137, 198, and 199 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Formal Matters***

1. Claims 1-120, 123, 124, 140, and 144 have been cancelled by Applicant. New claims 198 and 199 have been added. Claims 138, 139, 141-143, and 145-197 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 121, 122, 125-137, 198, and 199 are under examination. It is noted that SEQ ID NOs: 1 and 6 (as elected) were originally examined under a lack of unity restriction and were found to be free of the prior art. In light of this, SEQ ID NOs: 2, 3, 4, 7, 8, and 9 have now been rejoined and searched (see claims 134 and 135). In view of this rejoinder, this Office Action is NON-FINAL.

### ***Amendments to the Drawings***

2. The cancellation of drawing sheet 11 containing Figures 12a and 12b is acknowledged (Remarks, p. 20, second paragraph). Applicant is referred to the Petition Decision mailed 12/5/2007 regarding publication of preliminary amendments to the drawings. If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. It is noted that the republication of the instant application is US 2008/0064858 not 2008/0064848, as stated in Applicant's remarks. Information on how to effect drawing corrections is provided below.

### **Replacement Drawing Sheets**

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

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Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

**Annotated Drawing Sheets**

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

**Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

***Specification - Objection***

3. The disclosure is objected to because of the following informalities: the cancellation of Figures 12a and 12b from the drawings has not been reflected in the Brief Description of the Drawings in the specification. Specific amendment of the Brief Description of the Drawings cancelling these figures is required.

***Advisory Notice***

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but

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must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Response to Arguments***

***Claim Rejections/Objections Withdrawn***

5. The rejection of claims 121, 122, 125, 128, and 131 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn in light of Applicant's amendments.

***Claim Rejections/Objections Maintained***

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 121, 122, 125, 128, and 131 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/09137 (published 27 June 1991, cited in Applicant's IDS of 7/20/2005), for the reasons of record and the reasons set forth herein.

Applicant argues that the '137 publication does not teach isolated and/or purified human monoclonal antibodies (Remarks, p. 20, fifth paragraph). Applicant's argument has been fully considered, but it is not persuasive. The human monoclonal antibodies taught by the '137 publication are not recombinant antibodies, but they are isolated by the hand of man, therefore meeting the limitations of claims in the alternative (see pages 36-42, especially p. 39).

8. Claims 121, 122, and 128 remain rejected and new claim 199 is rejected under 35 U.S.C. 102(b) as being anticipated by Akamizu et al., (Endocrinology. 1999 Apr;140(4):1594-1601), for the reasons of record and the reasons set forth herein.

Applicant argues that the mere fact that these antibodies were isolated lymphocytes of a Graves' disease patient does not mean that they have the characteristics of "TSH receptor autoantibodies present in the serum of patients with hyperthyroid Graves disease" (Remarks, p. 20, last paragraph to page 21, first paragraph). Applicant argues that the reference information argues against an argument that they might inherently possess such properties (Remarks, p. 21, first paragraph). Applicant argues that the

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antibodies reported in the Akamizu paper have an affinity lower than what would be expected for autoantibodies associated with Graves' disease (Remarks, p. 21, last paragraph) and that Applicant's antibodies are more potent than the ones taught by Akamizu et al., (Remarks, p. 22, first paragraph).

Applicant's arguments have been fully considered, but they are not persuasive. Applicant's argument with regard to the "characteristics of TSH receptor autoantibodies" and their inherent properties are not substantiated by the claims, as written. The phrase "characteristics of TSH receptor autoantibodies" is vague and open to interpretation. Claims are read by the examiner in their broadest reasonable context. Characteristic of TSH receptor autoantibodies include that they are found in patients with Graves' disease and that they bind the TSH receptor. This alone is sufficient to meet the limitations of the claim, as written. Applicant's arguments with regard to affinity are spurious. There are no limitations in claims 121, 122, 128, or 199 that the antibodies have any particular binding affinity.

Akamizu et al., teach isolated and reconstituted the Ig genes of two B cell clones (101-2 and B6B7) producing a monoclonal thyroid-stimulating antibody (TSAb), a stimulating type of TSHRab (compare instant claim 199), obtained from human patients with Graves' disease (abstract) (compare instant claims 121 and 122). The activity of the human monoclonal antibodies to elevate cAMP levels in cells expressing TSHR is taught in Figures 3 and 4 (compare instant claim 128).

Applicant is also advised that because the Patent Office does not have the facilities to determine other "characteristics of TSH receptor autoantibodies," such as affinity the burden is on the application to show a novel and unobvious difference between the claimed antibodies and those of the prior art. See *In re Brown*, 59 CCPA 1036, 459 F.2d. 531, 173 USPQ 685 (CCPA 1972) (holding at 1041, "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith") and *Ex parte Gray*, 10 USPQ 2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.).

9. Claims 121, 122, 125-133 remain rejected and new claim 199 is rejected under 35 U.S.C. 102(b) as being anticipated by Kohn et al., (*J Clin Endo and Metab.* 1997;82(12):3998-4009), for the reasons of record and the reasons set forth herein.

Applicant argues the antibodies taught by Kohn et al., lack the characteristics of Graves' disease autoantibodies (Remarks, p. 22, second paragraph). Applicant argues that Table 5 of the present specification can be used to ascertain concentrations from units/weight and activity with regard to the inhibitory activity of claims 126, 127, 129, 130, 132, and 133 (Remarks, p. 22, third paragraph).

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Applicant argues that the activity of the Kohn et al., antibodies is less than the activity of the claimed antibodies (Remarks, p. 22, third paragraph).

Applicant's arguments have been fully considered, but they are not persuasive. Applicant's argument with regard to the "characteristics of TSH receptor autoantibodies" and their inherent properties are not substantiated by the claims, as written. The phrase "characteristics of TSH receptor autoantibodies" is vague and open to interpretation. Claims are read by the examiner in their broadest reasonable context. Characteristic of TSH receptor autoantibodies include that they are found in patients with Graves' disease and that they bind the TSH receptor. This alone is sufficient to meet the limitations of the claim, as written.

Kohn et al., teach antibodies from the sera of patients with Graves' (IgG) and the antibodies from the cloned heterohybridomas which are able to increase cAMP levels in cells expressing TSHR (Table 1, p. 4002; Figure 2, p. 4003) (compare instant claims 121, 122, 129, 130, and 133). Kohn et al., teach the ability of normal human IgG or the clonal stimulating TSHRABs to bind to human thyroid membranes in the presence of TSH, LH, or hGC (i.e. competitive binding assay) (Table 2, p. 4004; Figure 3, p. 4004) (compare instant claims 126, 127, and 132). Percent inhibition is also shown in a commercial TRAK assay in Table 3 (p. 4005) and Figure 4 (compare instant claims 126, 127, and 132). Table 4 (p. 4006) teaches the ability of the clones that have TBII activity to inhibit TSH or Graves' IgG-increased cAMP activity (see also Figure 5, p. 4006) (compare instant claims 121, 122, 125-133, and 199).

With regard to inhibitory activity levels of claims 126, 127, 129, 130, 132, and 133, Applicant admits that inhibition is achieved by at least one of the antibodies of the art at a concentration of 100 µg/ml, falling within the range limitations of the instant claims (Remarks, p. 22, third paragraph). As previously stated of record, absent evidence to the contrary, the human anti-TSHR monoclonal antibodies taught by Kohn et al., meet the limitations of the claims for the requisite comparative NIBSC units of activity. Because the Patent Office does not have the facilities to comparatively test the human anti-TSHR monoclonal antibodies taught by the art for the requisite comparative NIBSC units of activity, the burden is on the application to show a novel and unobvious difference between the claimed TSHR binding partners and that of the prior art. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (CCPA 1972) (holding at 1041, "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith") and *Ex parte Gray*, 10 USPQ 2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(c), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 136 and 137 remain rejected in addition to claims 121, 122, 125-133 and new claim 199 under 35 U.S.C. 103(a) as being unpatentable over Van Der Heijden et al., (Clin Exp Immunol. 1999;118:205-212) and Kohn et al., (J Clin Endo and Metab. 1997;82(12):3998-4009), as evidenced by WO 91/09137 (published 27 June 1991, cited in Applicant's IDS of 7/20/2005), UniProt, Accession No. P16473 (sequence version 1, 1 August 1990), and generally evidenced by Harlow et al., Eds. (Antibodies, A Laboratory Manual. Cold Spring Harbor Press. 1988, for the reasons of record and the reasons set forth herein.

Applicant argues that the antibodies of Kohn et al., do not meet the limitations of the claims because they do not meet the quantitative standard for inhibition of 30 units per mg (Remarks, p. 22, last paragraph). Applicant also argues that the difficulties in making antibodies, as evidenced by Exhibits D and E, must be taken into account in any assessment of obviousness (Remarks, p. 23, second paragraph).



Applicant's arguments have been fully considered, but they are not persuasive. Applicant has not presented any data or evidence beyond mere attorney argument that the quantitative standards of inhibition of Kohn et al., fall entirely outside the claimed range. As stated above and of record, absent evidence to the contrary, the human anti-TSHR monoclonal antibodies taught by Kohn et al., meet the limitations of the claims for the requisite comparative NIBSC units of activity (compare Tables 1-3, 5-7, 9-11, and 14-19 on pp. 78-81, 83-86, 88-91, and 95-102 of the instant specification). Because the Patent Office does not have the facilities to comparatively test the human anti-TSHR monoclonal antibodies taught by the art for the requisite comparative NIBSC units of activity, the burden is on the application to show a novel and unobvious difference between the claimed TSHR binding partners and that of the prior art. See *In re Brown*, 59 CCPA 1036, 459 F.2d. 531, 173 USPQ 685 (CCPA 1972) (holding at 1041, "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith") and *Ex parte Gray*, 10 USPQ 2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.).

With regard to Applicant's Exhibits D & E, they are noted. However, Applicant is reminded that the claims, as written, do not recite any specific "characteristics of TSH receptor autoantibodies." The phrase "characteristics of TSH receptor autoantibodies" is vague and open to interpretation. Claims are read by the examiner in their broadest reasonable interpretation. Characteristic of TSH receptor autoantibodies include that they are found in patients with Graves' disease and that they bind the TSH receptor. This alone is sufficient to meet the limitations of the claim, as written. Of the instantly rejected claims only claim 137 requires stimulatory activity of the TSHR antibody and even then it is only stimulatory with respect to cAMP production (as claimed). As previously stated of record, WO 91/09137 provides the rationale and motivation for human TSHR antibodies that can be practically and cost-effectively used as diagnostics and immunotherapeutics (Office Action mailed 4/1/2008, page 8, paragraph "h"). Exhibit D (Costagliola, et al., *Thyroid*. 2002; 12(12):1039-1041) states that at least three different groups were working on and developed TSH stimulating antibodies (p. 1039, column 2, second paragraph). This suggests that at the time of or prior to the instant invention researchers were well motivated and had reason to engage in routine experimentation to find and/or develop TSHR stimulating monoclonal antibodies. Additionally, the findings of the three groups showed that at least some of the monoclonals with TSABs activity were simultaneously endowed with TBII activity. "This was certainly not unexpected but formal proof was lacking." (p. 1040, last paragraph). Exhibit E (Ando et al., *Clin Devel Immunol.* Jun 2005;12(2):137-143) is noted as an after-filed reference. The abstract of Exhibit E also discusses only "pathologically relevant" stimulating TSHR monoclonal antibodies. Insofar as

Exhibit E is limited to a discussion of the "pathologically relevant" stimulating TSHR monoclonal antibodies, it is at odds with Applicant's Exhibit D, which states that at least three different stimulating TSHR monoclonal antibodies had been identified more than three years earlier than the one discussed in Exhibit E. Further, Exhibit E states that the monoclonal antibodies of Kohn et al., (1997) (cited as prior art in the instant rejection) showed stimulating or blocking activity at high concentrations (p. 139, second paragraph). The teachings of Kohn et al., of record, combined with the discussions in Applicant's Exhibit E and the fact that instant claim 137 does not recite an upper limit on the concentration amount of an antibody required for stimulatory TSHR activity, supports the examiner's position.

Without specific characteristics/limitations in the claims as to the "characteristics of TSH receptor autoantibodies," the art is sufficient to meet the limitations of the claims, as written, in their full scope and breadth. The examiner also notes that she is not requiring a recitation of all known characteristics of TSH receptor autoantibodies be added to the claims. However, if Applicant's antibodies embody characteristics that tend to show that they are unique from those found in the art, by, for example, possessing specific characteristics (that are supported by the specification, as filed) other than that they are found in patients with Graves' disease and that they bind the TSH receptor, the Applicant should consider these characteristics as limitations that are important enough to be added to the claims, so as to distinguish the claims over the prior art.

#### *New Claim Objections/Rejections*

##### *Claim Rejections - 35 USC § 112, Second Paragraph*

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 125 recites the limitation "patient serum TSH receptor autoantibodies" in line 2. There is insufficient antecedent basis for this limitation in the claim. Applicant's amendment to claim 121 removed the antecedent basis for this phrase in claim 125.

16. Claims 121, 122, 125-137, 198, and 199 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 121 recited the phrase "or is derived from" in line 2. The metes and bounds of the derivation are not defined in the claims or the specification such that one of ordinary skill in the art would be apprised of what Applicant intends or means by the phrase. Claims 122, 125-137, 198, and 199 are rejected as being dependent on a rejected claim.

***Advisory Notice***

17. SEQ ID NOs: 1, 3, 4, 5, 6, 7, 8, and 9 are free of the prior art as CDRs of VH or VL domains of antibodies. It is noted that the sequence of instant SEQ ID NO: 8 appears in some plant sequences in the prior art (search report in SCORE), but the art does not disclose the sequence in an antibody. Further, it is noted that the sequence of instant SEQ ID NO: 2 is known in the art as an antibody CDR (see sequence search report in SCORE). However, the art does not teach instant SEQ ID NO: 2 in an antibody that is a binding partner for a TSH receptor (see especially .rapm database, where SEQ ID NO:2 is only found in anti-Notch3 antibodies, anti-CD79b antibodies, and anti-IL-13 antibodies).

***Conclusion***

NO CLAIM IS ALLOWED.

This action is NON-FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:00am-5:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/  
Examiner, Art Unit 1647